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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,445	11/29/2001	Lexun Xuc	2896-4005	3445

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MORGAN & FINNEGAN, L.L.P.  
3 WORLD FINANCIAL CENTER  
NEW YORK, NY 10281-2101

EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,445

Applicant(s)

XUE ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,7,9 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,7,9 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 5 October 2004.
2. Applicant has cancelled claims 2-5, 8, 10 and 11, amended claims 1, 6, 7, and 9, and added new claims 12-14. Claims 1, 6, 7, 9, and 12-14 are pending, and are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

6. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the China, 00131217.0, filed 03 December 2000. Applicant has filed a certified copy of the priority document, EP99114074.0 application as required by 35 U.S.C. 119(b), and an English translation thereof.

### ***Claim Rejections - 35 USC § 112-2***

7. Claims 12-14 are rejected under 35 USC § 112-2 for the following reasons:

Claim 12 drawn to the method of claim 6, "wherein the transformation is by construction of an expression vector ....", does not make sense. Transformation by constructing a vector does not produce a transformed product.

In claim 14, (a), line 6, "the fusion gene" lacks antecedent basis.

***Claim Rejections - 35 USC § 112, first paragraph***

**Written description**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6, 7, 9, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 is drawn to a "fragment of TNF gene" (line 3). Claim 13 is drawn to "a cDNA fragment" (line 5) , and a "TNF cDNA fragment" (step e). Claim 14 is drawn to amplifying a "fragment" (line 3). The fragment length is unspecified, and may be as little as a single nucleotide .

However the specification does not disclose what structural features would be conserved in the claimed sequence that would result in the claimed activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the

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genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.ed 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have recognized Applicants to have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111).

***Claim Rejections - 35 USC § 112 Enablement***

10. Claim 1, 6, 7, 9, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record, set forth in the Office Action of 6 July 2004. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for preparing transgenic *Dunaliella Salina* by a foreign target gene selected from the group of TNF and HBsAg together with a selectable marker consisting of *aadA* gene, and a BAR gene.

Applicant's Guidance describes construction of an expression vector comprising a *Dunaliella Salina* Hsp70B 5' promoter and a hepatitis B antigen gene fusion with cholera toxin B (Specification, p. 14 line 6 bridging to p. 15 line 12), followed by introduction of this DNA into *Dunaliella Salina* cells via electroporation (specification, p.

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11, line 13-29). Applicant does not describe the production of transgenic *Dunaliella Salina*, which function as a bioreactor.

Applicant is invited to provide additional relevant information in the form of a §132 Declaration by the inventor or other appropriate person.

Experimentation required: Undue experimentation would be required to determine which foreign gene, derived from what source—plants, microorganisms, animal and humans, whether using genomic DNA or using cDNA for the coding sequence, what 5' regulatory sequence(s) would function as desired, be they constitutive or regulatable, and whether they need chloroplast or nuclear transcription machinery, so that they can be put into the appropriate organellar or nuclear location. For selectable markers, experimentation to determine what antibiotic agents, at what levels, in solid or liquid medium, would function as desired. Having made decisions based on these experiment parameters, experimentation would then be required how to introduce the DNA into the *Dunaliella Salina*—physical methods, such as electroporation or gene-gun, or biological methods such as *Agrobacterium* transformation, and whether the successful transformation be transient or stable. Another set of cascading experiments would be required to determine what foreign gene would function as desired for *Dunaliella Salina* functions to produce the desired product—are introns processed properly, does the gene have codon usage functional in *Dunaliella Salina*, is glycosylation proper since plant and animal glycosylation products differ, and is the product toxic to the transgenic *Dunaliella Salina*? Applicant must provide sufficient guidance to address these issues. Without such guidance the

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experimentation required would not be routine, but would be undue. This would impose a burden on the skilled artisan, without a reasonable expectation of success.

In view of the lack of guidance in the specification, the breadth of the claims ( all means of transformation including physical, chemical or biological methods) the nature of the invention, the unpredictability of the art, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Remarks***

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

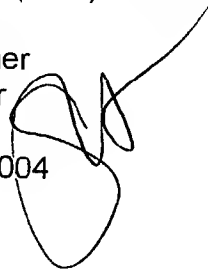
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
December 27, 2004



AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600